

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. With entry of this amendment, claims 1, 5, 6, 9 and 10 are pending, claims 2 - 4, 7, 8 and 11-48 are canceled and claim 1 has been amended. Claims 1 and 6 have been amended to overcome the rejections for indefiniteness.

Rejections Under 35 USC § 102 and 103

Applicants have amended the claims to recite that either isolated and purified Glycyrrhizic acid or isolated and purified Glycyrrhizin are present in the claims. Glycyrrhizin or glycyrrhizic acid is not the only constituent of the *Glycyrrhiza glabra* extract. As admitted by the Examiner, *Glycyrrhiza glabra* extract contains merely 7.05 to 9.30 % of glycyrrhizin or glycyrrhizic acid. *Glycyrrhiza glabra* extract also includes diglucuronic acid, triterpenoid saponins such as sitosterol and stigmasterol, flavonoids, isoflavonoids, isoflavone (also called as formononetin), coumestans, coumarins, tannin, starch and a bitter principle, which constitute the rest (90.70 to 92.95%) of the extract.

The Examiner indicates that US Patent '050 teaches combining licorice extracts with antibacterial agents. The Examiner further relies upon Takino to determine the concentration of glycyrrhizin that would inherently be present in the composition of US Patent '050. Finally, the Examiner concludes that the composition taught by US Patent '050 would inherently contain 1 µg/ml of glycyrrhizin and hence renders the present invention anticipated and obvious.

Applicants respectfully submit the combination of references cited by the Examiner would possess in addition to glycyrrhizin, all other ingredients of licorice listed above. On the contrary, the Applicants are claiming a composition which contains only isolated and purified glycyrrhizin and a conventional antibacterial agent and is devoid of all other ingredients of licorice. Thus, the composition of the present invention is entirely different

from the composition being taught in the cited references.

Therefore, in light of the following facts, the novelty and non-obviousness of the present invention is established.

US Patent '050 teaches that a combination of *Glycyrrhiza glabra* extract and cocamidopropyl dimethylglycine in which the amount of *Glycyrrhiza glabra* extract present is 15.6 µg/ml inhibits the growth of *Streptococcus mutans*. One of ordinary skilled in the art would not attribute the antibacterial property of the *Glycyrrhiza glabra* extract to a single ingredient of the extract based on the cited reference.

Glycyrrhizin is not known to possess any significant antibacterial activity. In fact, the antibacterial activity of the licorice or *Glycyrrhiza glabra* extract is attributed to isoflavonoids. Applicants have attached some references hereto to support this fact. (Exhibits A and B). Thus, even if a person skilled in the art refers to the cited document, he would be motivated to attribute the antibacterial property of the *Glycyrrhiza glabra* extract to isoflavonoids. In other words, a person skilled in the art would use isoflavonoids and not Glycyrrhizin for antibacterial activity. As can be seen from the present invention, the composition of the present invention recites only isolated and purified Glycyrrhizin and does recite or require any isoflavanoids.

In the present application, the applicants have clearly established that Glycyrrhizin *per se* is capable of enhancing the antibacterial activity of Rifampicin and Nalidixic acid to a larger extent as compared to the *Glycyrrhiza glabra* extract. In this regard, applicants wish to direct the Examiner's attention to some of the data already available in the tables of the present application. Table 10 indicates that when 10 µg/ml of Rifampicin is used along with 25 µg/ml of licorice, the combination shows 3.10 folds enhancement in antibiotic activity on *E coli*. However, as can be seen from Table 1, when 10 µg/ml of Rifampicin is used along with 1 µg/ml of Glycyrrhizin, the combination shows 3.80 folds enhancement in antibiotic activity. Similarly, Table 11 indicates that when 6 µg/ml of Nalidixic acid is used along with 25 µg/ml of licorice, the combination shows 4.10 folds enhancement in antibiotic activity on *Bacillus subtilus*. However, as can be seen from Table 2, when 6 µg/ml of Nalidixic acid is

used along with 1 µg/ml of Glycyrrhizin, the combination shows 4.50 folds enhancement in antibiotic activity on *Bacillus subtilis*.

Thus, it can be seen that the activity of Glycyrrhizin *per se* in enhancing the activity of the conventional antibacterial agent is greater than the activity of licorice. This is an unexpected property of the present invention which could not be predicted by the cited references. Therefore, the present invention is not obvious over the cited references and the rejections of record should be withdrawn. In view of the above, the claims of the present application should not be considered to be obvious over the combination of the documents.

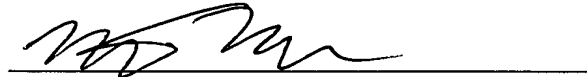
Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to

Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date January 21, 2005



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